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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA

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COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), through its undersigned attorneys, for its Complaint alleges

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1 Plaintiff FTC brings this action under Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U S C § 53(b), to secure injunctive relief and other equitable relief against Defendants for engaging in deceptive acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U S C §§ 45(a) and 52

JURISDICTION AND VENUE

- This Court has jurisdiction over this matter pursuant to 15 U S.C \$\$ 45(a), 52, 53(b) and 28 U S C \$\$ 1331, 1337(a), and 1345
- 3 Venue in this District is proper under 15 U S C § 53(b) and 28 U S C § 1391(b) and (c)

PLAINTIFF

4 Plaintiff, the Federal Trade Commission, is an independent agency of the United States Government created by statute 15 U.S.C. §§ 41-58. The Commission enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The Commission also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce. The Commission, through its own attorneys, may initiate

federal district court proceedings to enjoin violations of the FTC Act and to secure such equitable relief, including, rescission of contracts and restitution, and the disgorgement of ill-gotten gains caused by Defendants' law violations, as may be appropriate in each case 15 USC § 53(b)

DEFENDANTS

- Defendant National Urological Group, Inc ("NUG") is a closely held Alabama corporation with its principal office or place of business at 5675 Jimmy Carter Boulevard, Suite 720, Norcross, Georgia 30071 At all times relevant to the complaint, acting individually or in concert with others, NUG has advertised, marketed, distributed, and/or sold Lipodrene and Spontane-ES to consumers throughout the United States NUG transacts business in the Northern District of Georgia
- National Institute for Clinical Weight Loss, Inc. ("NICWL") was a closely held Alabama corporation with its principal office or place of business at 5675 Jimmy Carter Boulevard, Suite 720, Norcross, Georgia 30071. At all times relevant to the complaint, acting individually or in concert with others, NICWL advertised, marketed, distributed, and/or sold Thermalean to consumers throughout the United States. NICWL transacted business in the Northern

District of Georgia

- 7 Defendant Hi-Tech Pharmaceuticals ("Hi-Tech") is a closely held Georgia corporation with its principal office or place of business at 5675 Jimmy Carter Boulevard, Suite 720, Norcross, Georgia 30071. At all times relevant to the complaint, acting individually or in concert with others, Hi-Tech has advertised, marketed, distributed, and/or sold Lipodrene to consumers throughout the United States Hi-Tech transacts business in the Northern District of Georgia
- At all times relevant to this Complaint, acting individually or in concert with others, Mr. Wheat has formulated, directed, controlled, or participated in the acts or practices of NUG, NICWL, and Hi-Tech, including the acts or practices alleged in this Complaint. He transacts business in the Northern District of Georgia.
- 9 Defendant Thomasz Holda is an officer and/or director of NUG, NICWL, and Hi-Tech At all times relevant to this Complaint, acting individually or in concert with others, Mr. Holda has formulated, directed, controlled, or participated in the acts or practices of NUG, NICWL, and Hi-Tech, including the acts or practices alleged in this Complaint. He transacts business in the Northern District of Georgia.

- 10 Defendant Michael Howell was an officer and/or director of NUG and NICWL At all times relevant to this Complaint, acting individually or in concert with others, Mr. Howell formulated, directed, controlled, or participated in the acts or practices of NUG, and NICWL, including the acts or practices alleged in this Complaint. He transacted business in the Northern District of Georgia.
- Defendant Stephen Smith is an officer and/or director of NUG and NICWL At all times relevant to this Complaint, acting individually or in concert with others, Mr Smith has formulated, directed, controlled, or participated in the acts or practices of NUG and NICWL, including the acts or practices alleged in this Complaint. He transacts business in the Northern District of Georgia.
- Defendant Dr Terrill Mark Wright is at all relevant times to this

 Complaint a medical doctor licensed to practice by the State of Georgia Wright's

 business address is Doctor's Wellness Studio, Brook Hollow Shopping Center,

 5775 Jimmy Carter Blvd, Suite 200, Norcross, GA 30071 Wright has promoted

 Lipodrene, Thermalean and Spontane-ES in advertisements and promotional

 materials, including a direct mail piece that was distributed under his letterhead

 and over his signature. He transacts business in the Northern District of Georgia

COMMERCE

The acts and practices of defendants alleged in this Complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, $15~U~S~C~\S~44$

DEFENDANTS' COURSE OF CONDUCT

THERMALEAN

- Holda, Michael Howell, and Stephen Smith have manufactured, labeled, advertised, offered for sale, sold, and distributed Thermalean, a purported weight loss product, to the public Defendants primarily have advertised and offered Thermalean for sale through direct mail solicitations and the Internet web site www.thermalean com According to the product label, Thermalean contains sida cordifolia, a source of ephedrine alkaloids, kola nut, citrus aurantium, cassia nomame, green tea extract, and *5-HTP* Defendants have recommended that consumers take one Thermalean capsule an hour after breakfast and an hour after lunch A two-month (120 count) supply cost approximately \$81 95 plus \$8 00 for shipping and handling
 - 15 To induce consumers to purchase Thermalean, defendants NICWL

Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have disseminated or have caused to be disseminated advertisements for Thermalean, including but not necessarily limited to the attached Exhibits A and B. These advertisements contained the following statements

a

Introducing **Thermal**eanTM

(575 mg Capsule)

Three specific causes linked to obesity! with one solution Thermalean™

* * *

Clinical studies show the active components in ThermaleanTM yield the following extraordinary results

- Loss of up to 19% total body weight
- Increase metabolic rate by 76 9% without exercise!
- Reduction of 40-70% overall fat under the skin
- Loss of 20-35% of abdominal fat!

Thermalean™ promotes fat loss by over 600% without causing dangerous side-effects (and without a prescription!)

The Chemistry of **THERMA**LEAN™

If you take nothing else from this brochure — we urge you to understand the following

THIS IS THE MOST IMPORTANT POINT!!

The pharmaceutical drugs Xenical[®], Meridia[®], and Fastin[®] all address one aspect of obesity and <u>only</u> one aspect

* * *

At the National Institute for Clinical Weight Loss, Our research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia[®], Xenical[®], and Fastin[®] ThermaleanTM is the most complete, omni-faceted nutriceutical ever developed for the diet industry!

After four full years of product development and feedback from hundreds of thousands of participating clients, we are very proud to announce that **Therma**leanTM is the <u>FIRST</u> over-the-counter (O T C) nutriceutical to incorporate all three aspects of obesity into <u>one</u> amazing product called **Therma**leanTM and the results have been extraordinary .. <u>without side</u> effects¹

* * *

In their PRECISE RATIOS, the thermogenic components used in Thermalean™, have achieved the following results in University-sponsored clinical trials (all of these statistics have been reported in such professional journals as the International Journal of Obesity, American Journal of Clinical Nutrition, and The New England Journal of Medicine)

- ◆ 300% decrease in stored fat vs placebo
- ◆ 29% greater weight loss vs REDUX
- ♦ 600% increase in total weight loss v placebo
- ◆ 42% reduction in body fat in a specified time period

* * *

These three compounds coupled with a unique catechin in Thermalean™ have caused a 40 - 70% reduction in overall fat under the skin and a 20 - 35% loss of abdominal fat

* * *

Questions for Dr. Mark Wright M.D.

Q. Does Thermalean™ really work?

A. Yes **Therma**leanTM's scientifically proven formula has yielded the following results in independent university sponsored trials 42% reduction in body fat •300% decrease in stored fat •76 9% elevation in basal metabolic rate • 20 - 35% reduction in abdominal fat • 600% greater fat burning capabilities than placebo

Q. How much weight can I expect to lose with Thermalean^{TM?}

A. Clinical trials based upon ThermaleanTM's proprietary components have yielded weight loss to nearly 15% of beginning body weight within the first two months!

Example: (To put this statistic in perspective)

Starting Date	June 1st
Starting Weight	200 lbs
Weight after 60 days	170 lbs
Weight loss in 60 days	30 lbs

Why THERMALEAN™? Why Now?

THERMALEANTM is a product of decades of research and development in the field of weight loss! THERMALEANTM was designed to help the person only needing to lose 5 or 10 pounds, as well as the person needing to lose 100 or more pounds. Pharmaceutical "mega-firms" would have you believe their product is the only product to fight obesity. If this were true then why is America the most overweight society in the lustory of the world? With an estimated 75 million American's clinically considered obese—the question should be, Why not now?

* **

Drug Company Scandal Erupts side effects prompt FDA to ban Phen-fen

New <u>Safe</u> Alternative Just Released - Thermalean™ AVAILABLE WITHOUT PRESCRIPTION

* * *

NICWL is committed to providing the highest quality products available anywhere in the United States Through research and development Thermalean is the most effective tool for affecting [sic] rapid, safe and sustainable weight loss!

(Exhibit A Thermalean Print Brochure)

b

National Institute for Clinical Weight Loss 130 Inverness Plaza • Suite 203 • Birmingham, AL 35242 1-888-839-7962

From the desk of Dr Mark Wright M D Chief of Staff, NICWL,
American Medical Association,
American Society of Bariatric Physicians

Dear Friend,

The information contained in this literature is going to peak [sic] your attention!

* * *

Thermalean™ is a pharmaceutical-grade nutriceutical containing naturally occurring equivalents and substitutes for sibutramine (Meridia®), Orlistat (Xenical®), and Phentermine (Fastin®) in Thermalean™'s Core Pharmaceutical Composition and Formulation

* * *

ThermaleanTM's proprietary components have been proven to accomplish the following

- Inhibit Lipase for obesity management by inhibiting the absorption of dietary fats
- Slows the rate at which the body "metabolizes" serotonin therefore suppressing the appetite
- Safely increasing the metabolic rate without dangerous side-effects associated with prescription drugs

Thermalean™ was engineered upon cutting-edge <u>scientific</u> and <u>clinical</u> data which supports our claim that Thermalean™ is unmatched by any other prescription or non-prescription diet aid available

By approaching obesity with a proprietary nutriceutical rather than a new prescription drug our firm has foregone more than a billion dollars virtually guaranteed to any new prescription diet drug upon FDA approval!

* * *

The introduction of ThermaleanTM reflects the cumulative efforts of many top bariatric (weightloss) physicians, and researchers to bring the public a safe and effective scientifically-based formulation that <u>will</u> have a significant impact on your weight loss goals!

* * *

Try **Therm**alean[™] today and win the battle against obesity Again, do not delay! This is your chance to restore your health and confidence!

Sincerely

Mark Wright M D

(Exhibit B Thermalean Letter from Dr Wright)

(**Note:** Formatting of type and layout of excerpts above differs from original, some images omitted, for exact formatting see exhibits)

LIPODRENE

- 16 Since at least January 2001, defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have manufactured, labeled, advertised, offered for sale, sold, and distributed Lipodrene, a purported weight loss product, to the public Defendants primarily have advertised and offered Lipodrene for sale through direct mail solicitations but also through at least one print ad in a nationally distributed magazine. In addition, defendants have advertised and offered Lipodrene for sale on the Internet through the www cyclovar com website According to the product label, Lipodrene contains sida cordifolia, a source of ephedrine alkaloids, citrus aurantium, caffeine, coleus forskohlu, naringen, green tea, ginseng, and l-carnitine. Defendants have recommended that consumers take one Lipodrene tablet four to six times a day A 100-count bottle of Lipodrene cost approximately \$30 00 plus \$5 00 for shipping and handling
- To induce consumers to purchase Lipodrene, defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have disseminated or have caused to be disseminated advertisements for Lipodrene,

including but not necessarily limited to the attached Exhibits C through E. These advertisements contain the following statements

a

"Clinically PROVEN Weight Loss!"

* * *

- Lose up to 42% of your total body fat¹
- Lose up to 19% of your total body weight!
- Increase your metabolic rate up to 50%

LIPODRENE™ is a product you simply MUST TRY if you are having trouble losing weight . whether your weight loss goals involve 5lbs, 25lbs, or even 125lbs!

* * *

(Exhibit C. Cosmopolitan Magazine Ad)

b

LIPODRENETM

: PHASE I REVIEW

WARNER

Laboratories

PREPARED BY: Stephen D. Smith

Vice President, Director of Consumer Affairs

SYNOPSIS: Upon review of 25,000 women and men

participating in PHASE I trials, Lipodrene™ has shown to yield an 88% SUCCESS RATE with

virtually no side effects.

HISTORY:

On March 1, 1999, the professional staff and Medical Board at WARNER Laboratories aligned with one of the nation's largest

manufacturing facilities to begin **Phase I** testing of **Lipodrene™** an advanced, pharmaceutical-grade nutriceutical engineered to help women and men lose weight quickly and safely

(Exhibit D Lipodrene Direct Mail Insert)

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"Clinically PROVEN to be SAFE AND EFFECTIVE!"

- Lose up to 42% of your total body fat!
- Lose up to 19% of your total body weight¹
- Increase your metabolic rate up to 50%

The LIPODRENE™ technology is backed by Volumes of Independent Research and hundreds of Published studies by the most prominent

Universities and Medical Journals in the world

* * *

(Exhibit E Web page from www cyclovar com)

(**Note:** Formatting of type and layout of excerpts above differs from original, some images omitted, for exact formatting see exhibits)

Spontane-ES[™]

18 Since at least November 2002, Defendants NUG, Jared Wheat,
Thomasz Holda, Michael Howell, and Stephen Smith have manufactured,
labeled, advertised, offered for sale, sold, and distributed Spontane-ES, a
purported erectile dysfunction product, to the public Defendants primarily have

advertised and offered Spontane-ES for sale through direct mail solicitations, including free samples via mail—According to the product information, Spontane-ES contains Xanthoparmelia Scabrosa, Quebracho Extract (a source of yohimbine), L-Arginine, Mucuna Pruriens 20%, Ginko Biloba 24/6, Cnidium Monnier, and Epimedium 20% extract—Defendants have recommend that consumers take one to two tablets one hour prior to sexual activity—A 60-count supply costs approximately \$99.95, including shipping and handling

Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have disseminated or have caused to be disseminated advertisements for Spontane-ES, including but not necessarily limited to the attached Exhibit F. This advertisement contains the following statements

THE RIGHT MOVE
AGAINST SEXUAL DYSFUNCTION

Spontane-ES[™]

(Restoring Spontaneity to Making Love)

Primary Pharmacology How It Works

PRIMARY MECHANISM

Spontane-ES[™] is a revolutionary sexual stimulant engineered to <u>increase</u> <u>sexual stamina and arousal</u>. Unlike the competition, WARNER LABORATORIES uses only the highest grade extracts and nutriceuticals available in its raw material purchasing

* * *

Final Consideration

- 1) CAN **Spontane-ES**™ HELP ME? The results have been extraordinary with success rates as high as 90%!
- 2) CAN I TAKE Spontane-ES™ WITHOUT RISK TO MY HEALTH? The incidence of side effects is less than 3%¹

The active agents in Spontane- ES^{∞} have been shown in clinical trials to promote the following:

Immediate and spontaneous erections

Increased rigidity and duration of erections

* * *

- Q Is **Spontane-ES**[™] safe?
- A Extremely With five years worth of research and development in each component going into **Spontane-ES™** by the pharmacological staff at WARNER LABORATORIES we have not experienced any harmful side effects to date
- Q Can **Spontane-ES**[™] work for me?

A Yes, In preliminary testing **Spontane-ES**[™]'s active components have been shown to be effective in nearly 90% of all men who have taken it

(Exhibit F Spontane-ES[™] brochure)

(**Note:** Formatting of type and layout of excerpts above differs from original, some images omitted, for exact formatting see exhibits)

THE FTC ACT

20 Section 5(a) of the FTC Act, 15 U S C § 45(a), prohibits unfair or deceptive acts or practices in or affecting commerce. Section 12(a) of the FTC Act, 15 U S C § 52(a), prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U S C § 52, Lipodrene, Thermalean, and Spontane-ES are either a "food" or "drug" as defined in Sections 15(b) and (c) of the FTC Act, 15 U S C §§ 55(b), (c) As set forth below, Defendants NUG, NICWL, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have engaged and/or are continuing to engage in such unlawful practices in connection with the advertising, marketing and sale of Lipodrene, Thermalean, and Spontane-ES

UNFAIR OR DECEPTIVE ACTS OR PRACTICES IN VIOLATION OF THE FTC ACT

COUNT I

False Claims for Thermalean

- Through the means described in Paragraph 15, including through the statements contained in the advertisements attached as Exhibits A and B, Defendants NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that
 - a Thermalean is clinically proven to be an effective treatment for obesity,
 - b Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months,
 - c Thermalean is clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months,
 - d Thermalean is clinically proven to enable users to lose 19% of total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76 9%, and
 - e Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects

22 In truth and in fact

a Thermalean is not clinically proven to be an effective

treatment for obesity;

- b Thermalean does not cause rapid and substantial weight loss, including as much as 30 pounds in 2 months,
- c Thermalean is not clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months.
- d Thermalean is not clinically proven to enable users to lose 19% of total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%, and
- e Thermalean is not clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects

Therefore, the making of the representations set forth in Paragraph 21 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 USC \$\$ 45(a) and 52

COUNT II

Unsubstantiated Claims for Thermalean

23 Through the means described in Paragraph 15 above, including through the statements contained in the advertisements attached as Exhibits A and B, Defendants NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and

Stephen Smith have represented, expressly or by implication, that:

- a Thermalean is an effective treatment for obesity,
- b Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months,
- Thermalean causes users to lose 19% of total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76 9%,
- d Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects,
- e Thermalean is equivalent or superior to the prescription weight loss drugs Xenical®, Meridia®, and Fastin® in providing weight loss benefits; and
- f Thermalean is safe
- Defendants NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 23 above, at the time the representations were made. Therefore, the making of the representations set forth in Paragraph 23 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U S C §§ 45(a) and 52

COUNT III

False Claims for Lipodrene

- 25 Through the means described in Paragraph 17, including through the statements contained in the advertisements attached as Exhibits C through E, Defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that
 - a Lipodrene causes substantial weight loss, including as much as 125 pounds,
 - b Lipodrene is clinically proven to enable users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%,
 - c Lipodrene is clinically proven to be safe, and
 - d Lipodrene is clinically proven to cause virtually no side effects

26 In truth and in fact

- a Lipodrene does not cause substantial weight loss, including as much as 125 pounds,
- b Lipodrene is not clinically proven to enable users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%,
- c Lipodrene is not clinically proven to be safe, and
- d Lipodrene is not clinically proven to cause virtually no side

effects

Therefore, the making of the representations set forth in Paragraph 25 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U S C §§ 45(a) and 52

COUNT IV

<u>Unsubstantiated Claims for Lipodrene</u>

- 27 Through the means described in Paragraph 17 above, including through the statements contained in the advertisements attached as Exhibits C through E, Defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that
 - a Lipodrene causes substantial weight loss, including as much as 125 pounds,
 - b Lipodrene enables users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%, and
 - c Lipodrene is safe
- Defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 27 above, at the time the

representations were made. Therefore, the making of the representations set forth in Paragraph 27 above, constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U S C §§ 45(a) and 52

COUNT V

False Claims for Spontane-ES

- Through the means described in Paragraph 19, including through the statements contained in the advertisement attached as Exhibit F, Defendants NUG, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that
 - a Spontane-ES is clinically proven to be effective in treating 90% of men with erectile dysfunction,
 - b Spontane-ES is clinically proven to be effective in treating men with erectile dysfunction, and
 - c Spontane-ES is clinically proven to cause no harmful side effects

30 In truth and in fact

- a Spontane-ES is not clinically proven to be effective in treating 90% of men with erectile dysfunction,
- Spontane-ES is not clinically proven to be effective in treating men with erectile dysfunction, and

c Spontane-ES is not clinically proven to cause no harmful side effects when used as directed.

Therefore, the making of the representations set forth in Paragraph 29 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 USC \$\$ 45(a) and 52

COUNT VI

Unsubstantiated Claims for Spontane-ES

- Through the means described in Paragraph 19, including through the statements contained in the advertisement attached as Exhibit F, Defendants NUG, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that,
 - a Spontane-ES is effective in treating erectile dysfunction in 90% of users, and
 - b Spontane-ES is safe
- 32 Defendants NUG, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 31 above, at the time the representations were made. Therefore, the making of the representations set

forth in Paragraph 31 above, constitutes a deceptive practice, and the making of a false advertisement, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C §§ 45(a) and 52

COUNT VII

False Endorsement Claims

- 33 Defendant Terrill Mark Wright, M D , has made statements, including statements as an expert endorser, in advertisements and promotional materials for Thermalean, including but not limited to statements contained in the advertisements attached as Exhibits A and B
- 34 Through the use of the statements referred to in Paragraph 15 defendant Wright has represented, directly or by implication, that
 - a Thermalean is clinically proven to be an effective treatment for obesity,
 - b Thermalean is clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months,
 - Thermalean is clinically proven to enable users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76 9%, and
 - d Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects

35 In truth and fact

- a Thermalean is not clinically proven to be an effective treatment for obesity,
- b Thermalean is not clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months,
- Thermalean is not clinically proven to enable users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76 9%, and
- d Thermalean is not clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects

Therefore, the making of the representations set forth in Paragraph 34 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 USC $\S\S$ 45(a) and 52

COUNT VIII

Lack of Reasonable Basis for Expert Endorsement

36 Through the use of the statements contained in the advertisements and promotional materials referred to in Paragraph 15, Defendant Wright has represented, directly or by implication, that

- a Thermalean is an effective treatment for obesity,
- b Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months,
- Thermalean causes users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76 9%,
- d Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects,
- e Thermalean is equivalent or superior to the prescription weight loss drugs Xenical®, Meridia®, and Fastin® in providing weight loss benefits, and
- f Thermalean is safe
- Defendant Wright did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 36 at the time the representations were made. Moreover, Defendant Wright did not exercise his purported expertise as a physician, in the form of an examination or testing of the Thermalean product at least as extensive as an expert in that field would normally conduct, in order to support the conclusions in the endorsement. Therefore, the making of the representations set forth in Paragraph 36 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U S C

§§ 45(a) and 52.

COUNT IX

False Claims Regarding Research and Medical Facility

- 38 Through the means described in Paragraphs 15, 17, and 19

 Defendants NUG, NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and

 Stephen Smith have represented, expressly or by implication, that Warner

 Laboratories and NICWL are bona-fide research or medical facilities that engage
 in scientific or medical research and testing at on-site physical facilities
- In truth and in fact, Warner Laboratories and NICWL are not bona fide research or medical facilities that engage in scientific or medical research and testing at on-site facilities. Therefore, the making of representation set forth in Paragraph 38 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U S C §§ 45(a) and 52

<u>INJURY</u>

40 Consumers throughout the United States have suffered and continue to suffer substantial monetary loss as a result of Defendants' unlawful acts or practices. In addition, Defendants NUG, NICWL, Hi-Tech, Jared Wheat,

Thomasz Holda, Michael Howell, and Stephen Smith have been unjustly

enriched as a result of their unlawful practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

41 Section 13(b) of the FTC Act, 15 U S C § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of the FTC Act. The Court, in the exercise of its equitable jurisdiction, may award ancillary or other relief, including, but not limited to, rescission of contracts and restitution, and the disgorgement of ill-gotten gains caused by Defendants' law violations

PRAYER FOR RELIEF

WHEREFORE, Plaintiff FTC requests that this Court, as authorized by Section 13(b) of the FTC Act, 15 U S C § 53(b), and pursuant to its own equitable powers

(a) Permanently enjoin Defendants from violating Sections 5(a) and 12 of the FTC Act, 15 U S C §§ 45(a) and 52, in connection with the offer, sale, advertising, or other promotion or distribution of weight-loss products, erectile function products, or any food, drugs, dietary supplements, devices, cosmetics,

or other products, services, or programs,

- (b) Award all temporary and preliminary injunctive and ancillary monetary relief that may be necessary to avert the likelihood of consumer injury during the pendency of this action, and to preserve the possibility of effective final relief, including, but not limited to, preliminary injunctive relief,
- (c) Award such equitable relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, including, but not limited to, rescission of contracts and restitution, and the disgorgement of ill-gotten gains, and
- (d) Award the Plaintiff the costs of bringing this action, and such other equitable relief as the Court may determine to be just and proper

Dated

November 10, 2004

Respectfully submitted,

WILLIAM E KOVACIC General Counsel

TAWANA E DAVIS

SYDNEY M KNIGHT

EDWARD GLENNON

FEDERAL TRADE COMMISSION

601 New Jersey Avenue, NW,

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Introducing



(575 mg Capsule)

Three specific causes linked to obesity! with one solution Thermalean



Clinical studies show the active components in Thermalean" yield the following extraordinary results:

- . Loss of up to 19% of total body weight
- Increase metabolic rate by 76.9% without exercise!
- Reduction of 40-70% overall fat under the skin
- Loss of 20-35% of abdominal fat1

Thermalean™ promotes fat loss by over 600% without causing dangerous side-effects (and without a prescription!)

The Chemistry of Thermalean"

If you take nothing else from this brochure we urge you to understand the following

THIS IS THE MOST IMPORTANT POINT!

The pharmaceutical drugs Xenical*, Meridia*, and Fastin* all address one aspect of obesity and only one aspect

- Xenical® Inhibits the absorption of dietary fats
- Meridia*- Suppresses the appetite by blocking the re-uptake of Serotonin
- Fastin* Burns fat by increasing the metabolic rate

Each of these novel pharmaceuticals attack one aspect of obesity, but neglect to address the other causes of obesity!

At the National Institute for Clinical Weight Loss, Our research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia*, Xenical*, and Fastin* Thermalean* is the most complete, omni-faceted nutriceutical ever developed for the diet industry!

After four full years of product development and feedback from hundreds of thousands of participating clients, we are very proud to announce that Thermalean is the FIRST over-the-counter (OTC) nutriceutical to incorporate all three aspects of obesity into one amazing product called Thermalean and the results have been extraordinary without side effects!

Give Thermalean a try

Thermalean" and "Thermogenesis" or fat burning!

In life there are certain things known as "constants" "truths" facts upon which you can always rely in the study of obesity there is one absolute—one "constant"

If a person does not 'burn" more calories than he/she takes-in, then weight loss is IMPOSSIBLE!

ANY drug or nutriceutical indicated for weight-loss that fails to address this issue is incomplete—and cannot be counted upon to provide sufficient support for ANYONE sincerely struggling with a weight problem

Thermalear "s NUMBER ONE strength lies in its potent thermogenic compound

Because of Thermalean 's advanced fat loss catalyst, the product development team at National Institute for Clinical Weight Loss, Inc. has absolutely 'toed-the-line" with respect to the FD A 's restrictions on thermogenic components You can be SURE that, while we do fall within the FD A 's margin of safety." there is NO OTHER PRODUCT ON THE MARKET ANYWHERE with a stronger fat-burning," thermogenic component than Thermalean '!

In their PRECISE RATIOS, the thermogenic components used in Thermalean*, nave achieved the following results in University-sponsored clinical trials (all of these statistics have been reported in such professional journals as the International Journal of Obesity. American Journal of Clinical Nutrition, and The New England Journal of Medicine)

- ♦ 300% decrease in stored fat vs. placebo.
- ◆ 29% greater weight loss vs. REDUX
- ♦ 600% increase in total weight loss vs. placebo.
- 42% reduction in body fat in a specified time period

Thermalean "'s ability to safely increase the metabolic rate vs. Fastin".

It is no secret why, as we get older, our weight and body fat percentages begin to rise. **The answer** A sluggish metabolism that seems to grow slower and slower with each passing year!

The central challenge facing professionals world-wide is, again, the potential for side-effects associated with the most effective catalyst for metabolic elevation. Fastin® and other amphetamine products ordinarily produce harsh side effects such as nervousness, inability to sleep, and nausea.

Until Thermaiean such side-effects that make Fastin and other true thermogenic products unbearable for a large percentage of the population (for reasons ranging from high blood pressure to diabetes)

Thermalean overcomes this challenge!!!

Researchers at the National Institute for Clinical Weight Loss have isolated three chemical compounds that effectively increase the metabolic rate by 76.9%. Since our metabolic catalyst does not cross the blood-brain barrier like Fastina it does

not risk the possibility of abuse or becoming habit forming! Upon consumption of Thermalean the thyroid hormone converts from an inactive state to an active state directly increasing the Resting Metabolic Rate (RMR)



Fat mobilization occurs within minutes of taking Thermalean™ as the body increases production of Brown Adipose Tissue (BAT) — A special tissue that actually burns fat rather than storing it

This means by taking Thermalean your body will effectively and safely burn fat around the clock regardless of your food intake or level of exercise!

Thermalean™ and Serotonin Elevation



Serotonin plays a critical role in every person's effort to maintain a healthy weight or to lose excess pounds. In fact, Serotonin is

so crucial, it has been the <u>focus</u> of such prescription drugs as Redux, Fenfluramine (1/2 the Phen-fen combination), and Meridia® (currently the #1 prescription diet drug in the world)

Meridia* has been welcomed by physicians and millions of overweight patients. When it was first introduced to the market, Knoll Pharmaceuticals (manufacturers of Meridia*) had 180 million capsules pre-ordered at \$4.00 each. That is an initial revenue of \$720 million before it was proven to be effective!

Additionally, Serotonin enhancement serves as the key "player" in the treatments of such emotional and psychological dysfunctions as depression and bulimia (an extreme form of carbohydrafe addiction)

Note: <u>Thermalgan</u>"'s Serotonin "mobilizer" can be taken safely with such SSRI drugs as Prozac, Paxil, Zoloft. Wellbutrin and Celexa

Clearly Serotonin can not be overlooked when formulating an effective weight loss and diet aid And, with respect to Serotonin, Thermalean answers the call!

Thermalean" works much like the way Meridia works Thermalean" slows the rate at which the body "metabolizes" Serotonin (a process known as Serotonin re-uptake) Thermalean" offers the patient an extraordinary tool for appetite suppression

Thermalesn" and Food Intake -Clinical Trials/Comparisons

Thermalean works to correct Serotonin imbalances within the brain that lead to headaches, depression, sleeplessness, and, most importantly for weight management, uncontrollable food cravings - especially for carbohydrates!

Hunger is a complex sensation that scientist know is directly fied to brain chemistry, not just our stomachs! In particular, carbohydrates are responsible for the vast majority of weight problems. That's because carbohydrates cause the production of insulin, allowing tryptophan to enter the brain. Tryptophan stimulates the production of serotonin, which regulates our body weight and makes us feel good. But there's one big problem!

Until the release of Thermalean", fattening, figure destroying carbohydrates were the only <u>natural</u> Serotonin stimulant for that happy, comfortable feeling. Unfortunately, this carbohydrate stimulated high lasts only a short time, encouraging further intake of snack foods, potato chips, pastries, and sweets which are <u>all</u> carbohydrates. This is the sad vicious circle that leads to obesity. It is this subconscious desire to <u>feel good</u> that causes people to eat more carbohydrates and thus gain weight!

The following results from a clinical trial were recently reported on the success of **Thermalean** 's Serotonin-enhancing component

NICWL	· (FB00 INTAKE calories/day)	PROTEINS INTAKE (Grants/Bay)	CARBONYONATE INTAKE (prams/day)
Prior to Treatment	Ī	2.903	101	274
Placebo Recipients	í	2.327	85	223
Thermalean * Recipients	! !	1.819	79	176

These patients were not asked to consciously reduce food consumption or increase daily activity.

LET'S PUT THESE EXCITING RESULTS INTO PERSPECTIVE

A person who reduces calories to this extent would 'osa a whopping 73 pounds in a year!

Thermalean™ and Inhibiting the Absorption of Dietary Fats.

One of the novel approaches to weight loss is inhibiting the absorption of dietary fats. Xenical (Orlistat) is currently is a lipase inhibitor for obesity management that acts by inhibiting the absorption of dietary fats and is extremely useful for patients with hypertension, hyperlipidemia, and diabetes

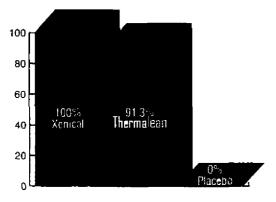
Xenical* is only successful for obese patients with an initial body mass index (BMI) of 30 or more

Lipase inhibitors are expected to be candidates of medicines for prevention or treatment of obesity and/or accompanying various adult diseases (Currently there are 18 lipase inhibitors in the pipeline for FDA approval for obesity alone) This confirms just how effective lipase inhibitors are Thermalean "contains the only herb that inhibits lipase - Cassia Nomame

You may have tried various "fat blocking" products before, but they were all based around an ingredient known as <u>Chitosan</u> Chitosan's research led companies to believe it was an effective "fat blocker." but 'real life" results show this not to be the case <u>Chitosan has actually caused many patients to gain weight instead of lose weight because of false advertising!</u>

In fact many companies have been put out of business for their "false claims" regarding Chitosan or fined millions of dollars!

Lipase Inhibiting Activity



Flavan Dimers with Liapse Inhibitory Activity From Cassia Nomame

Five flavan dimers which show lipase - inhibiting effects have been isolated from fruits of Cassia Nomame. The most effective tested for lipase - inhibitory activity was (2S) - 3,4, 7 - Trihydroxy. Flavan - (4a - 8) - Catechin Thermalean uses the highest grade Cassia Nomame in the world! (A 10.1 Extract imported from Europe as demonstrated in the Certificate of analysis below).

How does Cassia Nomame work?

When we consume an excess amount of fat, our body stores it for future use as a fuel source, resulting in weight gain. Our bodies use enzymes to break down fats into their simplest components so that they can be absorbed. These enzymes are called lipases and they work by not allowing the body to absorb fats efficiently, therefore not being stored. Thermalean incorporates a one of a kind. Cassia Extract testing positive for 2.03% (Flavano dimers), 3.04% (Flavanoids), and 4.01% (OPC)

These three compounds coupled with a unique catechin in Thermalean have caused a 40 - 70% reduction in overall fat under the skin and a 20 - 35% loss of abdominal fat

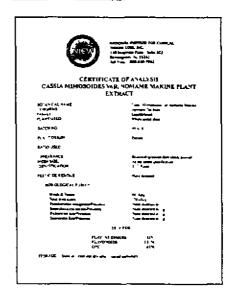


EXHIBIT A-5

Questions and Answers the most common concerns

Q. How is Thermalean taken?

A. Delivered in easy to swallow capsules.

Thermalizan" is taken twice daily, preferably one (1) an hour after breakfast and one (1) an hour after lunch

Doctors note Thermalean will work regardless of the timing of the dosage. This is only to try to establish a consistent time to take Thermalean.

Q. How long do I need to take Thermalean *2

A. Thermalean should be taken until your desired weight loss goals are met. The ultimate duration is entirely dependent upon the amount of weight you need to lose (5, 10, 50, 100 pounds or more).

Q. Who should or should not use Thermalean ??

A. Thermalean" is intended to help women and men who have difficulty losing weight. Unlike prescription medications, Thermalean" will work regardless of the amount of weight you need to lose. Thermalean" has a strong record of safety and is virtually safe for all people. If you are pregnant or lactating you should not take Thermalean."



Q. What about side effects?

A. Extensive research has been done on the active components in Thermalean, and no evidence suggests short or long - term use poses any health risks

Questions for Dr. Mark Wright M.D.



Q. Does Thermalean" really work?

A. As a Bariatric physician (weight loss physician) my job is to help people lose weight. I have endorsed other good dietary supplements, as well as prescribed Xencial®, Meridia®, and Fastin®/phentermine over the past decade. I consider

myself an expert in the field of weight loss, and never before have I seen a product (prescription or non-prescription) that is so complete Thermalean addresses every aspect that is critical in losing weight, and does so economically 1 think Thermalean is the product American's have been looking for to solve their weight problems. With 75 million americans clinically considered "obese", Thermalean could not have come at a better time Does Thermalean "really work? Yes Thermalean"'s scientifically proven formula has yielded the following results in independent university. sponsored trials 42% reduction in body fat • 300% decrease in stored fat • 76 9% elevation in basal metabolic rate • 20 - 35% reduction in abdominal fat • 600% greater fat burning capabilities than placebo

Q. How much weight can I expect to lose with Thermalean 7

A. Clinical trials based upon Thermalean sproprietary components have yielded weight loss to nearly 15% of beginning body weight within the first two months.

Example (To put this statistic in perspective)

the beautiful to the second of		
Starting Date	June 1°	
Starting Weight	200 lbs	
Weight after 60 days	170 lbs	
Weight loss in 60 days	30 lbs	

Why Thermalean *? Why Now?

Thermalean" is a product of decades of research and development in the field of weight loss!

Thermalean" was designed to help the person only needing to lost 5 or 10 pounds, as well as the person needing to lose 100 or more pounds. Pharmaceutical "mega-firms" would have you believe their product is the only product to fight obesity. If this were true—then why is America the most overweight society in the history of the world? With an estimated 75 million American's clinically considered obese—the question should be, Why not now?

More than half of all adults and 11 percent of all children and adolescents in the United States are estimated to be overweight or obese <u>David Satcher M D , Ph D and U S Surgeon General declared obesity a "nationwide epidemic" and held a Nation Action Plan on Overweight and Obesity, December 8, 2000</u>

CONSIDER THE FACTS

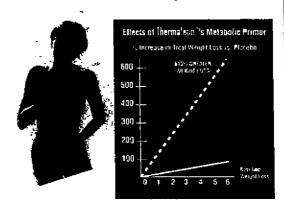
Heart disease - Nearly 70% of the diagnosed cases of cardiovascular disease are related to obesity

High blood pressure - obesity more than doubles your chance of developing high blood pressure, which affects approximately 26% (over 19 million people) of obese American men and women

Other diseases - Obesity is significantly linked to diabetes, heart disease, hypertension, stroke, breast cancer, gallbladder disease, elevated cholesterol levels and arthritis, just to name a few

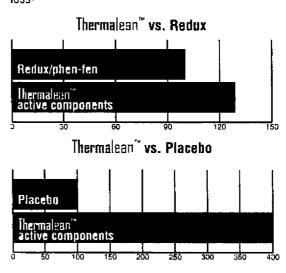
Death - Obese people are twice as likely to die prematurely as those of normal weight

Technical Discussion and Statistical Findings on Thermalean™'s Metabolic Catalysts.



Unprecedented Fat Burning Abilities! (Above)
Thermalean contains a metabotic primer which has been proven in clinical trials to increase weight loss by more than 600% vs. placebo! These results were printed in the Journal of the American College of Nutrition. Thermalean is clearly the most advanced fat-burner available!

(Below) Thermalear." active metabolic catalyst has also proven to safely outperform Redux/Phen-fen as reported in the *International Journal of Obesity*, as well as burn fat causing 300% more weight loss!



MEDICAL



Drug Company Scandal Erupts side effects prompt FDA to ban Phen-fen

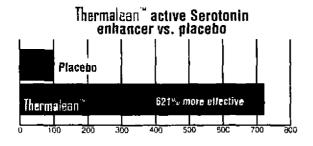
New <u>Safe</u> Alternative Just Released - Thermalean*
AVAILABLE WITHOUT PRESCRIPTION

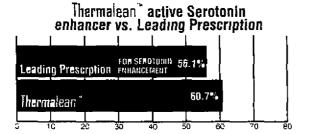
in September 1997 the United States Food and Drug Administration officially banned the use of Redux and Phen-fen for weight control Everyone including medical professionals, thought Phen-fen was the answer to obesity. They were all dangerously wrong!

Scientists at Johns Hopkins University Medical Center discovered that users of Phen-fen developed swelling of neurons deep within their brains. It was also found to be the cause of abnormal heart valve function that, after a few months usage, produced pulmonary hypertension.

New Thermalean" is Safe and Natural...

A clinical study performed at the University of Rome on Thermaliean serotonin-enhancing component produces impressive results on weight loss vs. placebo as well as outperforming the leading prescription drug for serotonin enhancement.





ORDER TODAY!!!

To order Thermalean

- Simply complete the Order Form enclosed and return the completed form along with your check, money order, or credit card information in the reply envelope provided
- OR Simply call our 24-Hour Toll Free Order Line at 1-888-839-7962

(Automated Ordering is available 24 hours)

For questions or concerns regarding Thermalean*, please call during normal business hours, 9 am to 7 pm E S T Our trained Customer Care Professionals are eager to assist you!

100% MONEY BACK GUARANTEE!!!

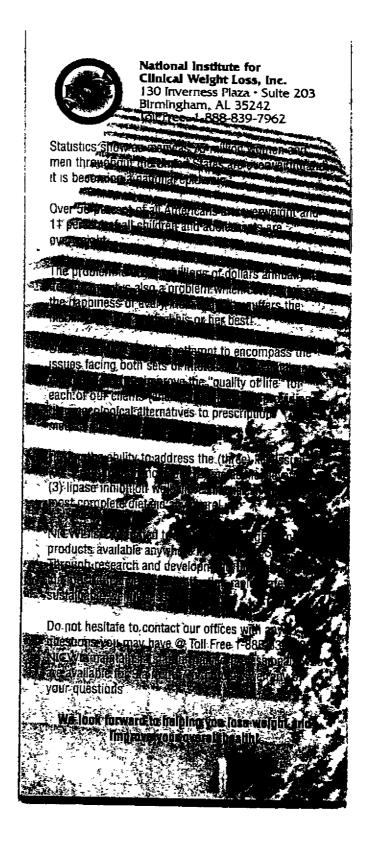
no questions asked!!!

Thermalean will work for you or we will give your money back!

If for ANY reason you are not completely thrilled with Thermalean or with the level of customer service you receive from NICWL, Inc., then you may simply return your unused portion within the first 30 days for a COMPLETE refund of the product price, including shipping and handling! NO QUESTIONS ASKED!

Our commitment to you begins the DAY you receive your product, once you begin taking Thermalaan of you have ANY questions or concerns, we strongly encourage you to contact our offices! We are eager to assist you in any manner possible

Professional Acknowledgment: Thermalean was not designed to cure, treat, or diagnose any disease. All references to journals, organizations, doctors, studies, research and the like are independent of NICWL inc and Thermalean."





National Institute for Clinical Weight Loss 130 Inverness Plaza Suite 203 • Birmingham, AL, 35242 1-888-839-7962

From the desk of Dr. Mark Wright M.D. Chief of Staff, NICWL, American Medical Association, American Society of Bariatric Physicians

Dear Friend.

The information contained in this literature is going to peak your attention! I strongly encourage you to consider the scientific data supporting this information—and, most particularly, to carefully read the report entitled

"Naturally Occurring Equivalents and Substitutes for Sibutramine (Meridia*), Orlistat (Xenical*), and Phentermine (Fastin*) in Thermalean"'s Core Pharmaceutical Composition and Formulation"

With that said, I would like to introduce you to Thermalean." a product that works unlike <u>any</u> over-the-counter (O T C) drug or supplement ever introduced (Thermalean is a DSHEA - classified supplement)

Thermalean[™] is a pharmaceutical-grade nutriceutical containing naturally occurring equivalents and substitutes for sibutramine (Meridia[®]). Orlistat (Xenical[®]), and Phentermine (Fastin[®]) in Thermalean[™]'s Core Pharmaceutical Composition and Formulation (as the above referenced report and enclosed brochure will detail and support.)

Without going into a technical discussion here, let's simply say Thermaleer is the most complete product on the market today for rapid sustainable weight loss by combining (3) proven technologies for weight loss into one revolutionary diet aid!

Thermalean* has the ability to effect each of the (3) primary weight loss concerns by addressing each unique aspect with a nutriceutical specifically engineered to accomplish its goal

Thermalean"'s proprietary components have been proven to accomplish the following

- . Inhibit Lipase for obesity management by inhibiting the absorption of dietary fats
- Slows the rate at which the body "metabolizes" serotonin therefore suppressing the appetite
- Safely increasing the metabolic rate without dangerous side-effects associated with prescription drugs

Thermalean was engineered upon cutting-edge <u>scientific</u> and <u>clinical</u> data which supports our claim that Thermalean™ is unmatched by any other prescription or non-prescription diet aid currently available

By approaching obesity with a proprietary nutriceutical rather than a new prescription drug our firm has foregone more than a billion dollars virtually guaranteed to any new prescription diet drug upon FDA approval!

Our primary concern is bringing the safest, most effective diet aid to the 80 million Americans who are 20% or more above their ideal body weight. With the countless life-threatening diseases directly linked to obesity time was of the essence.

With the decade or so length to acquire a patent coupled with the growing number of Americans who are overweight we decided to take the nutriceutical approach

The introduction of Thermalean* reflects the cumulative efforts of many top barratric (weight loss) physicians, and researchers to bring the public a safe and effective, scientifically-based formulation that will have a significant impact on your weight loss goals!

I see patients every day and prescribe effective drugs such as Meridia®, Xenical®, and Phentermine I have also endorsed dietary supplements in the past that I thought had merit in weight reduction, but I have never been so enthused about a product as I am with Thermalear 1 It is the answer to anyone needing to lose weight regardless of the amount. Whether you need to lose 10, 20, 100 pounds or more Thermalean will work for you. We are so confident in Thermalean we are offering a True 100% Money Back Guarantee! If Thermalean does not work for you we will refund every penny including shipping and handling. This leaves you with nothing to risk, but your health. No other pharmaceutical company or nutrition company has this offer currently, because they do not believe in their product the way we do in Thermalean "

Try Therma ear today and win the battle against obesity. Again, do not delay! This is your chance to restore your health and confidence!

Sincerely

Mark Wright M D

Mark Why to

MONEY BACK GUARANTEE

If you are not completely happy with Thermalsan return the unused portion within (30) days from the day you receive your package for a <u>FULL</u> refund including Shipping and Handling. No questions asked!!!

EXHIBIT B-2





'Clinically PROVEN Weight Loss!'

Lipodrene^{1M} technology is backed by volumes of Independent Research and hundreds of published studies by the most prominent. Universities and Medical Journals in the world.



Lipodrene^M: PHASE I REVIEW

Upon review of 25,000 participants in the PHASE! trials, Lipodrene™ has been shown to yield an 88% SUCCESS RATE with virtually no side effects.

	88% Completely	11.7%	< 1% Experienced
100%	Satisfied	Dissalisfied	Side-Effects
80%			
60%			
40%			
20%			
0%	E:EUD Memor	- Mon Portici	nyted in Phase I

To order your 2 month supply of Lipodrene for \$89.95 call 1.888.661.0047 or send a check or money order to: Warner Laboratories, 4107 Portsmouth Boulevard #101 Ste 97. Chesapoake, VA 23321.



4107 Portsmouth Boulevard #101 Suite 97 Chesapeake, Virginia 2002 Toll Free: 1 388 661-0047

- Lose up to 42% of your total body fat!
- Lose up to 19% of your total body weight!
- Increase your metabolic rate up to 50%

TO ORDER, CALL: 1-888-661-0047

or visit: www.warnerlaboratories.com

from Dr. Mark Wright, M.D. - Medical Director for Warner Laboratories

I would like to introduce a compound that works unlike any prescription or over the counter (O T.C.) weight loss aid voubleve example the Γ

Lipodreneth is a pharmaceut call-grane weight less termula containing the fall-burning technology proven to be 29% more effective than Reduces devicently raining.

If you are like the nellions of Americans each year trying to remain unders healthy physique. I strongly encourage you to consider the information on this page?

Lipodrene¹³ was developed exclusively by the medical and pharmacological team at WARNER Laboratories and represents the cultinitation of our work with more than 120,000 women and men throughout the United States.

Lipodrene¹⁹ is a product you simply MUSTIRY if you are having trouble come weight . . whether your weight loss goals involve blue, 25lbs, or even 125lbs.

As the fluctrations below show, **Lipodrene**rd is based upon the process of statistating "ipolynic", the release of laty and serves to which "t<u>pograpess</u> the prerate of har

Specifically, **Lipodrene¹⁴** inhibits the release of targeted encytnes that control to exprage white also stimulating collular energy it offsetwoly causing the individual for cells to release volumous rand unwanted) righty acids.

PLEASE UNDERSTAND ... Lipodrene^{1/2} is not just another diet pill!

Why Lipodrene™ Succeeds when Calorie-restriction Fails

Our bodies are designed to store fait for times when nounshment may be unavailable. When we deprive ourselves of nounshment (in an effort to lose weight), our motocolish allows almost to a half as a means to preserve fat (energy) in case the period of deprivation is lasting.





: PHASE I REVIEW

4107 Portsmouth Boulevard #101 - Suite 97 • Chesapeake, Virginia 23321 • 1-888-661-0047

Filed 11/10/04 Page 44 of 48



PREPARED BY Stephen D. Smith

Vice President, Director of Consumer Affairs

SYNOPSIS: Upon review of 25,000 women and men participating in the PHASE I trials,

Lipodrene™ has shown to yield an 88% SUCCESS RATE with virtually no side effects

HISTORY:

On March 1, 1999, the professional staff and Medical Board at WARNER Laboratories aligned with one of the nation's largest manufacturing facilities to begin Phase I testing of Lipodrene™, an advanced, pharmaceutical-grade nutriceutical engineered to help women and men lose weight quickly and safely

NVE Pharmaceuticals, manufacturers of Lipodrene™ and its proprietary immediate-release delivery system, was selected by WARNER Laboratories for two reasons 1) NVE played a critical role in the research and Development phase, contributing countless man-hours to the development of a highly-specialized metabolic catalyst 2) NVE is one of the few facilities in the United States capable of meeting the production demands projected for the national release of Lipodrene™, beginning in 2001 (upon release of the Phase I Review)

RESEARCH AND DEVELOPMENT

Our vision for Lipodrene™ was two-tiered 1) To find the most effective, synergistic combination of nutriceutical compounds available for the stimulation of metabolic activity (serving as an affective fat-releasing agent for anyone needing to lose weight) 2) To find an advanced delivery system, such as Explotab®, that will dramatically improve and accelerate Lipodrene™ fat loss capabilities

NVE Pharmaceuticals response to our expressed objectives was exceptional. The end result of an exhausting Research and Development phase was Lipodrene™ (encapsulating our vision perfectly)

The R&D team at NVE introduced a proprietary immediate-release delivery method developed by Penwest Pharmaceuticals Explotab® is incorporated into the Lipodrene™ formula to provide rapid and uniform tablet absorption and drug dissolution With the Explotab® delivery, Lipodrene™ is quickly and efficiently absorbed in tact, ensuring maximum availability of the active components and ensuring maximum potency

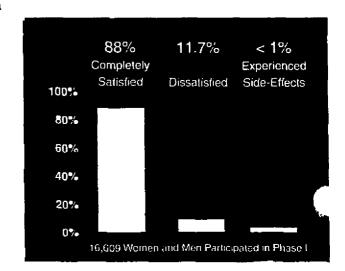
Without an advanced delivery system, such as Explotab®, most pharmaceutical tablets lose up to 90% of their potency

through liver and gastric absorption. With Lipodrene™, we are sure to be delivering nearly 100% of the active components a measure which helps tremendously in maintaining the integrity of our research and product claims

Lipodrene™ was designed to facilitate the promotion of "lipolysis" (the release of fat) while inhibiting "lipogenesis" (the storage of fat) Additionally, Lipodrene™ suppresses the appetite, reduces cravings and stimulates thyroid metabolism

Following are the Phase I Distribution Results

No of Participants	16,609
No of Reported Side Effects	20
No Reporting Dissatisfaction	1,931
No. Reporting Complete Satisfaction	14.658



: PHASE II LAUNCH



4107 Portsmouth Boulevard #101 - Suite 97 • Chesapeake, Virginia 23321 • 1-888-661-0047



PHASE II LAUNCH ANNOUNCED

On December 1, 2000 Board members of WARNER Laboratories, Chief of Staff, Dr Timothy Gaginella, and members of NVE Pharmaceuticals conferred to discuss the compiled data from the Phase I Launch of **Lipodrene^{TM's}** proprietary compound

All participants in the discussion agreed the 88% Success Rate, coupled with an extremely low incidence of side effects, was indicative of an exceptionally high-ranking oit c. nutriceutical

Dr Gaginella, in his prepared remarks for the Phase I Review noted **Lipodrene™** appears to be void of any significant or problematic side effects. Furthermore, Dr Gaginella pointed to the technology's following accomplishments in clinical trials.

- 300% increase in weight loss when dieting (vs. dieting alone)
- 50% increase in metabolic rate without exercising
- 42% reduction in total body fat
- 19% reduction in total body weight
- 29% MORE weight loss vs dexfenfluramine (Redux®)

Dr Gaginella believes **Lipodrene™**, coupling its near-negligible rate of side effects with its extraordinary high success rate, should be considered by anyone experiencing difficulty in losing weight as a "first-line" of action

Given the exceptional results from the Phase I Review, WARNER Laboratories, in cooperation with NVE Pharmaceuticals, has chosen to move forward in an aggressive promotion of **Lipodrene™** to the national market

PREPARATIONS for PHASE II DEMAND

NVE Pharmaceuticals has increased its annual production capabilities to several billion **Lipodrene™** tablets, ensuring WARNER Laboratories' ability to meet consumer demand

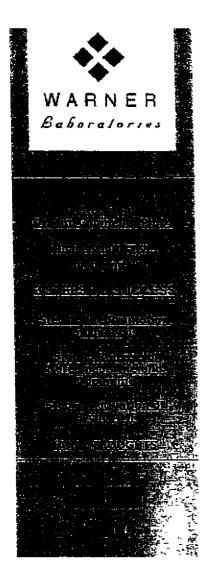
WARNER Laboratories' doubled its Customer Service staff and nearly doubled the size of its Customer Service offices. Customer Support has been placed as the No. 1 objective for the 2001 Phase I Launch

"With an unprecedented 88% Success Rate during Phase I testing and estimates from the U.S. Surgeon General that nearly 50% of ALL American adults are at least 20% overweight, first year sales of **Lipodrene™** are expected to projected to have an unparalleled impact on the weight loss industry

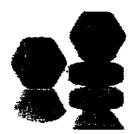
National polling has shown that in the year 2000, nearly 70 MILLION Americans tried some form of weight loss program—over 40 MILLION of those women and men were unsuccessful

We, at WARNER Laboratories, believe Lipodrene™ can change the landscape

Throughout Phase I testing, clients reported success with Lipodrene™ when other products had repeatedly failed



CONTACT US | ORDER LIPODRENETM | ORDER CYCLOVARTM



"Clinically PROVEN to be SAFE AND EFFECTIVE!"

- Lose up to 42% of your total body fatl
- Lose up to 19% of your total body weight!
- Increase your metabolic rate up to 50%

The LipodreneTM technology is backed by Volumes of Independent Research and hundreds of Published studies by the most prominent Universities and Medical Journals in the world, including.

University of Chicago - International Journal of Obesity
 American Journal of Clinical Nutrition New England Journal of Medicine

Letter from the Doctor

Dear Friend,

It is with tremendous confidence that I introduce to you an OTC sexual aid that YOU will want to

TORIES and is the most advanced sexual aid I have

but, rather, to strongly recommend you give these sam-Because of we have provided you with TWO sample tablets to try for yourself My job is not to convince you to invest in this product our supreme confidence in Spontanc-FS In this instance, my job is quite easy!

ABORATORIES we have not be

armocological staff at WAR

Once you have sampled Spontane-CS you will understand Try the samples provided, and secure your order TODAY Future orders could be delayed due to excessive demand

sungary (3) side effects to prescription

nedications and (4) Drabetes

Complications resulting from pears

to E.D are (1) spicator of common physical proWishing you the very best of health and vitality

Chesapeake, Virginia 23321 4107 Portsnouth Blvd #101 Surte 97

I've nothced a decrease in libido Will

0

Spontane-ES help?



pontane - E

introduce to your friends!

Spontane-E5 was developed by WARNER LABORA ever had the opportunity to review ple tablets a try absolutely RISK FREE

parmella Scabrosa) is imported from China exclusively for WARNER LABORATORIES Xanthoparmella Scabrosa is in One thing I also encourage you to do is act (Xartho QUICKLY! The active ingredient in Spontane-EST Imited supply

75-80% of al

occurrences of E.D. physiological digital

can Spointane-ES work for

Dr Mark Wright, M.D.

components have been shown to be

Spontane-ES's octive

Yes, in preliminary testing

iffective in nearly 90% of all men

who have taken t

WARNER LABORATORIES Toll Free 1-888-666-1386



Spontanely to Making Love)



Exhibit F-1

proven to increase libido, even il you

don't have ED

different components that have been

Yes, Spointane-ES contains 4

PRIMARY PHARMACOLOGY

How It Works

* PRIMARY MECHANISM

Unlike the competition, WARNER LABORATORIES uses only the highest grade extracts and nutriceuticals available in its raw engineered to increase sexual stamina and Spontane-ES is a revolutionary sexual stimulant material purchasing

Spontane-LS uses proprietary components not found anywhere else in America 1) Xanthoparmella Scabrosa - induces smooth muscle relaxation in the penis, allowing for maximum arterial dilation and increased blood flow

ighted below), Xanthoparmelia Scabrosa offers significant support for any man experiencing Combined with the secondary components (hidifficulties with erectile function

SECONDARY PHARMACOLOGY

Also included in Spontanc-CS are the following timetested sexual aids

- 2) Quebracho Extract Quebracho increases blood flow to the penis and dramatically increases libido The Quebracho used in Spontane-Es contains the highest percentage yohimbine found in the world! Again, beware of the competition! Products containing inferior quebracho have NO yohimbine rendering it useless!
- L-Arginine Increases production of nitric oxide, leading to a more rigid erection
- 4) Mucuna Prunens 20% Increases dopamine levels, igniting a euphoric feeling and increasing sensations during orgasm



5) Gingko Biloba 24/6 - Increases circulation and blood flow

unlike anything else in nature and is imported 6) Chidium Monnier - elevates nitric oxide levels exclusively for the manufacture of Spontane-E5

7) Epimedium 20% extract - Increases libido and what is currently being sold on the market to elesex drive. This extract is 20 times stronger than vate the libido

Xanthoparmelia Scabrosa, these components Quite possibly, you are familiar with many of the Secondary ingredients used in Spantane-ES They yield minimal results! when used in coordination with provide valuable support in the formation and are often used as Primary mechanisms for O TC maintenance of an erection sexual aids and at best However

CONCLUSION

Why Now?

RESULTS SPEAK LOUDER THAN WORDS

Undoubtedly, you have tried other O TC products for the support of erectile function. Have you ONCE been given the opportunity to SAMPLE the product before investing your money? We are SO confident in sydname-ES, that we have sent, along with this information, TWO tablets for

you will become a committed client? If, by chance, it does not on have lost NOTHING!

It is SIMPLE

YOU WILL BE CONVINCED TRY IT ONCE... FOR FREE

HINAT CONSIDERATION

Xanthoparmelia Scabrosa is classified under the Federal DSHE Act and CAN be used in OTC nutriceutical production! Spontane-ES is the most advanced nutriceutical to with the secondary components, helps us to utilize this component for the support of healthy erectile function and when used synergistically confidently answer our clients most common questions

The results have been extraordinary with success rates as high as 90%! CAN Spontane-ES HELP ME?

7

The incidence of side effects is less than 3%! CAN I TAKE Spontane-ES WITHOUT RISK TO MY HEALTH?

 $\widehat{\alpha}$

The only side effect ever reported is mild nervousness, dizziness or heart palpitations. If these occur, discontinue use of Spontane-US The active agents in Spointane-ES have been shown in clinical trials to promote the following:

- Immediate and spontaneous erections
- increased rigidity and duration of erections
- Increased strength of orgasm

disease. The statements contained in this information have not Spántane-ES' was not designed to treat, cure or diagnose any been evaluated by the Food and Drug Administration IMPORTANT HEALTH PRECAUTIONS



Exhibit F-2